UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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April 8, 1985

#19

Mr. Donald J. Barrack
E. R. Squibb & Sons, Inc.
Worldwide Hqs.
P. O. Box 4000
Princeton, NJ 08540

Re: Patent Term Extension Application
U.S. Patent 4,217,347

An application for patent term extension of U. S. Patent No. 4,217,347 issued August 12, 1980, was filed on December 7, 1984. The basis for the application is said to be 35 USC 156. The application was filed on behalf of the patent owner E. R. Squibb & Sons, Inc.

The application states that the patent claims a product, Capozide, that was subject to regulatory review under section 505 of the Federal Food, Drug and Cosmetic Act (21 USC 355). This product is said to have received permission for commercial marketing or use under 21 USC 355 on October 12, 1984. Based on these assertions, notice of receipt of the extension application and a copy of the application were sent by the Patent and Trademark Office to the Secretary of Health and Human Services on January 31, 1985.

The application identifies the product approved under section 505 of the Federal Food, Drug and Cosmetic Act as Capozide. The approved product contains a combination of captopril and hydrochlorothiazide as the active ingredients. The New Drug Application for Capozide (NDA 18-709) was approved on October 12, 1984. A letter from Dr. Stuart L. Nightingale, Associate Commissioner for Health Affairs of the Food and Drug Administration (FDA) dated March 18, 1985 (copy attached) indicates that a review of FDA official records shows that NDA 18-709 does not represent the first permitted commercial marketing or use of the active ingredients, captopril and hydrochlorothiazide. According to those records, these active ingredients, were previously approved for marketing as follows: Capoten tablets (Captopril, 25 mg. NDA 18-343) was approved on April 6, 1981, and hydrochlorothiazide is a drug that is the subject of several new drug applications that were first approved prior to 1962. These products were subject to a regulatory review under section 505 of the Federal Food, Drug and Cosmetic Act before approval for commercial marketing or use was obtained. Based on this information, it is concluded that the approval of Capozide as NDA 18-709 on October 12, 1984 was not the first permitted commercial marketing or use of either active ingredient - captopril and hydrochlorothiazide - under section 505 of the Federal Food, Drug and Cosmetic Act.

The statutory provision permitting an extension of the patent term if the product covered by the claims in the patent has been subject to a regulatory review period before its commercial marketing or use (35 USC 156(a)(4)) is qualified in section (a)(5)(A) by the provision that the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred. Whether the approval of Capozide is considered to be the first permitted commercial marketing or use of the product depends on the meaning that should be attributed to "product" to be consistent with the legislative intent of 35 USC 156.

The term product is defined in 35 USC 156(f) as including a human drug product. A human drug product is defined as the active ingredient of a new drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug and Cosmetic Act and the Public Health Service Act). The human drug product may be commercially marketed or used as a single entity or in combination with another active ingredient.

The active ingredients marketed in combination in Capozide - captopril and hydrochlorothiazide - have each been the subject of a prior regulatory review. Since a human drug product is defined as the active ingredient used as a single entity (e.g. captopril) or in combination with another active ingredient (e.g. captopril and hydrochlorothiazide), it is concluded that the approval of Capozide on October 12, 1984 was not the first permitted commercial marketing or use of the product under section 505 of the Federal Food, Drug and Cosmetic Act.

According to the report of the House Committee on Energy and Commerce, the approved product must have been approved for commercial marketing for the first time, with one exception not applicable to the facts in this application. H.R. Rep. 98-857, Part 1, 98th Cong., 2d Sess. 37-38 (1984). Extensions are required to be based on the first approval of a product according to the report because the only evidence which was available to Congress showing that patent time has been lost is data on so-called class I, new chemical entity drugs. These drugs had been approved by the FDA for the first time.

Also significant in the determination of legislative intent is the fact that during deliberations by the Committee on the Judiciary, an amendment proposed by Congressman Hughes was rejected. According to House Report 98-857 Part 2, supra at 7-8: "The Hughes amendment would have permitted the granting of a patent term extension for the substances regulated by the bill

for each regulatory review period. The net result of the amendment was to permit multiple patent term extensions on what was essentially the same drug product." In rejecting the Hughes amendment, the Committee on the Judiciary accepted the rationale put forward by the Committee on Energy and Commerce concerning the need to avoid multiple patent term extensions.

Under the circumstances of this application, the Patent and Trademark Office concludes that U. S. Patent 4,217,347 is not eligible for extension of the patent term under 35 USC 156. The approval to use captopril and hydrochlorothiazide (the active ingredients) in Capozide under section 505 of the Federal Food, Drug and Cosmetic Act on October 12, 1984, was not the first permitted commercial marketing or use of either captopril or hydrochlorothiazide under that provision of law.

The application for extension of the term of U. S. Patent 4,217,347 is DENIED.

C. E. Van Horn

Charles E. Van Horn, Director
Patent Examining Group 120

Attachment: Letter Dated March 18, 1985
from Dr. Stuart L. Nightingale